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Evaluation of a Personalized Approach to Inhaled Corticosteroid Dosing in Asthma Based on Exhaled Nitric Oxide Levels: A Prospective Study

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Abstract:

Background: Asthma management traditionally follows standardized step-up/step-down approaches, but growing evidence suggests that personalized treatment strategies may improve outcomes. Fractional exhaled nitric oxide (FeNO) serves as a valuable biomarker of airway inflammation, potentially guiding individualized inhaled corticosteroid (ICS) dosing. The study aims to evaluate the efficacy of a FeNO-guided approach to ICS dose adjustment compared to standard guideline-based care in achieving optimal asthma control.

Methods: In this 12-month prospective, randomized controlled trial, 240 adults with persistent asthma were allocated to either FeNO-guided or guideline-based ICS dosing. The FeNO-guided group underwent monthly dose adjustments based on predetermined FeNO thresholds, while the control group followed standard clinical guidelines. Primary outcomes included time to first exacerbation and changes in Asthma Control Test (ACT) scores.

Results: FeNO-guided participants demonstrated significantly lower annual exacerbation rates (0.38 vs 0.52 events/patient-year, $p<0.001$) and higher mean improvement in ACT scores (3.2 vs 2.1 points, $p=0.008$). Overall ICS consumption was reduced by 27% in the FeNO-guided group without compromising control.

Conclusion: FeNO-guided ICS dosing represents an effective strategy for personalizing asthma management, resulting in improved clinical outcomes and optimized medication use. This approach warrants consideration for integration into routine clinical practice.

Keywords: Exhaled Nitric Oxide (FeNO), Asthma Management, Inhaled Corticosteroids, Personalized Medicine, Dose Optimization, Biomarker-guided Therapy

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INTRODUCTION

Asthma affects approximately 339 million people worldwide, presenting a significant public health challenge that demands innovative management approaches (Global Initiative for Asthma [GINA], 2023). Despite advances in therapeutic options and established treatment guidelines, achieving optimal disease control remains elusive for many patients (Price et al., 2021). The traditional approach to asthma management, based on symptoms and lung

function, may not adequately address the underlying inflammatory pathophysiology that characterizes the disease (Pavord et al., 2022).

The emergence of biomarker-guided therapy represents a paradigm shift in asthma management, offering the potential for more personalized treatment approaches (Szefler et al., 2020). Fractional exhaled nitric oxide (FeNO) has emerged as a particularly promising biomarker, providing a non-invasive measure of airway inflammation that correlates well with eosinophilic activity and responsiveness to inhaled corticosteroids (ICS) (Hanania et al., 2023). Recent years have witnessed growing interest in utilizing FeNO measurements to guide asthma therapy, particularly in adjusting ICS dosing (Wang et al., 2021). This approach aligns with the broader movement toward precision medicine, where treatment decisions are tailored to individual patient characteristics rather than following a one-size-fits-all protocol (Brightling & Bhavsar, 2022). Several studies have suggested that FeNO-guided treatment may improve asthma outcomes, though results have been heterogeneous and questions remain regarding optimal implementation strategies (Petsky et al., 2021).

The relationship between FeNO levels and airway inflammation is well-established, with elevated levels typically indicating active eosinophilic inflammation amenable to corticosteroid therapy (Heaney et al., 2023). Normal FeNO levels in adults typically range from 5 to 25 parts per billion (ppb), with values above 50 ppb strongly suggesting active airway inflammation (American Thoracic Society [ATS], 2023). This quantitative marker offers potential advantages over traditional clinical parameters in guiding ICS dosing decisions (Turner et al., 2021). Previous research has demonstrated several key findings that inform our current study:

1. FeNO levels show strong correlation with airway eosinophilia and respond predictably to anti-inflammatory therapy (Castro et al., 2023)
2. Elevated FeNO levels often precede clinical deterioration in asthma control (Busse et al., 2022)
3. Reduction in FeNO levels following ICS initiation or dose increase typically indicates therapeutic response (Lazarus et al., 2023)
4. Normal FeNO levels in well-controlled patients may identify opportunities for ICS dose reduction (Israel & Reddel, 2023)

Despite these promising observations, significant knowledge gaps remain regarding the optimal implementation of FeNO-guided therapy in routine clinical practice (Menzies-Gow et al., 2023). Questions persist about appropriate FeNO thresholds for treatment decisions, optimal monitoring frequency, and cost-effectiveness of this approach (Khurana et al., 2022).

MATERIALS & METHODS

***Study Design and Participants*:** This prospective, randomized controlled trial was conducted following the CONSORT guidelines (Moher et al., 2021) across three university-affiliated asthma clinics from March 2022 to February 2023. The study design was adapted from previously successful biomarker-guided trials (Domingo et al., 2022) and modified to address identified methodological limitations (Singh et al., 2023).

Eligible participants included adults aged 18-75 years with physician-diagnosed persistent asthma requiring daily ICS therapy, following validated diagnostic criteria (Reddel et al., 2023). The inclusion and exclusion criteria were established based on recent international consensus guidelines (GINA, 2023) and recommendations from systematic reviews of biomarker-guided therapy (Petsky et al., 2022).

***Randomization and Intervention*:** Participants were randomized 1:1 to either FeNO-guided or guideline-based care using computer-generated block randomization stratified by baseline ICS dose, following validated randomization protocols (Schulz & Grimes, 2022). The randomization process was conducted using REDCap electronic data capture tools (Harris et al., 2023).

The FeNO-guided group underwent monthly FeNO measurements using standardized techniques with the NIOX VERO analyzer (Circassia), following ATS/ERS recommendations for FeNO measurement (Graham et al., 2023). ICS

doses were adjusted according to a protocol developed based on previous successful trials (Honkoop et al., 2022) and expert consensus guidelines (Dweik et al., 2023):

FeNO Level (ppb)	Action	Supporting Evidence
>50	Increase ICS dose one step	Turner et al., 2023
25-50	Maintain current dose	Price et al., 2023
<25	Decrease ICS dose if controlled for ≥3 months	Reddel et al., 2023

The control group received standard care following Global Initiative for Asthma (GINA) guidelines (2023), with treatment adjustments based on symptoms, lung function, and exacerbation history, as outlined by Pavord et al. (2023).

Inclusion and Exclusion Criteria

***Outcome Measures and Assessment*:** Primary outcomes were selected based on their clinical relevance and validation in previous biomarker studies (Castro et al., 2023):

1. Time to first asthma exacerbation, defined according to ATS/ERS criteria (Reddel et al., 2023)
2. Change in Asthma Control Test (ACT) scores from baseline, using the validated minimal clinically important difference of 3 points (Israel et al., 2023)

***Secondary outcomes included*:**

1. Annual exacerbation rate
2. Cumulative ICS dose
3. Lung function changes (FEV1)
4. Quality of life measured by AQLQ (Juniper et al., 2022)

Statistical Analysis: Sample size calculation was performed using G*Power 3.1 (Faul et al., 2023), determining that 240 participants (120 per group) would provide 80% power to detect a 40% reduction in exacerbation rate at α=0.05, accounting for an anticipated 15% dropout rate (Wang et al., 2023). Analysis followed intention-to-treat principles using appropriate statistical tests for continuous and categorical variables (Gamble et al., 2022).

Ethical Considerations

Before initiating the research, the Institutional Review Board Shri Mahant Indiresh Hospital, Dehradun examined and endorsed the study protocol. The investigation adhered to the ethical standards outlined in the Declaration of Helsinki and followed Good Clinical Practice guidelines throughout its execution.

RESULTS

The baseline characteristics demonstrate well-balanced randomization between FeNO-guided and standard care groups, with no statistically significant differences Table 1. Mean age (45.3 vs 44.8 years), gender distribution (60% vs 58.3% female), and BMI (27.4 vs 27.8) were comparable between groups. Importantly, baseline lung function (FEV1 78.5% vs 77.9% predicted) and FeNO levels (39 vs 41 ppb) showed minimal variation. Initial ACT scores (16.8 vs 16.5) indicated suboptimal control in both groups, aligning with the target population for intervention. This balanced distribution strengthens the validity of subsequent outcome comparisons.

Table 2 demonstrates significant improvements in the FeNO-guided group across all outcomes. Primary outcomes show longer time to first exacerbation (HR: 0.68, p=0.004) and greater ACT score improvement (3.2 vs 2.1 points, p=0.008). Secondary outcomes reveal a 27% reduction in annual exacerbation rate (0.38 vs 0.52 events/year, p<0.001) and substantial ICS dose reduction (186 µg/day difference, p<0.001). Lung function improved more in the FeNO-guided group (+4.2% vs +2.8% FEV1, p=0.024).

Table 3 reveals distinct outcomes across FeNO categories. Low FeNO (<25 ppb) patients (35%) achieved successful ICS reduction with minimal

exacerbation risk (0.22/year) and highest ACT improvement (+3.8). Intermediate FeNO (25-50 ppb) group (38.3%) maintained stable doses with moderate risk (0.35/year). High FeNO (>50 ppb) patients (26.7%) required dose escalation and showed highest exacerbation risk (0.58/year) despite treatment intensification. This stratification demonstrates FeNO's utility in guiding personalized treatment decisions.

Figure 1 demonstrates the relationship between FeNO levels and ICS dosing patterns over 12 months. The FeNO-guided group showed progressive reduction in ICS dosing (from 815 µg/day to 512 µg/day) while maintaining disease control, as evidenced by the concurrent decline in FeNO levels (from 39 ppb to 26 ppb). In contrast, the standard care group maintained relatively stable ICS doses (798 µg/day to 770 µg/day). The divergent patterns between groups (27% reduction in FeNO-guided vs 3.5% reduction in standard care) suggest that FeNO-guided dosing enables more efficient ICS titration without compromising control.

The graph illustrates three key findings:

1. Successful ICS dose reduction in the FeNO-guided group without loss of control
2. Strong correlation between FeNO levels and required ICS dosing
3. Potential overtreatment in the standard care group, as evidenced by stable high doses despite low FeNO levels

This data supports FeNO-guided therapy as a strategy for optimizing ICS dosing while maintaining effective asthma control.

Figure 2 illustrates the dynamic relationship between FeNO levels and exacerbation risk over 24 weeks. Initially, FeNO levels were relatively stable (42-45 ppb) with low exacerbation risk (14-15%). A notable spike occurs at week 12, where FeNO levels exceed the critical threshold of 50 ppb (reaching 55 ppb), corresponding with a marked increase in exacerbation risk from 18% to 25%. A gradual decline follows this peak in both parameters, though exacerbation risk remains elevated (28%) at week 16 despite decreasing FeNO levels. The red reference line at 50 ppb highlights clinically significant FeNO elevations requiring intervention. The temporal lag between FeNO elevation and peak exacerbation risk (approximately 4 weeks) suggests a predictive window for preventive interventions. This pattern demonstrates the predictive value of FeNO monitoring in anticipating asthma exacerbations and supports its utility as a biomarker for guiding preventive treatment adjustments.

The **figure 3** demonstrates the longitudinal relationship between observed and predicted FeNO levels over 12 months. The observed FeNO levels (purple line) show a consistent downward trend from 45 ppb at baseline to 31 ppb at month 12. The predicted values (green dashed line) closely track the observed measurements, indicating good model fit. The 95% confidence intervals (gray bands) narrow over time, suggesting increased prediction accuracy. This decline in FeNO levels correlates with improved asthma control under the intervention protocol.

Table 1: Baseline Characteristics

Characteristic	FeNO-Guided Group (n=120)	Standard Care Group (n=120)
Age, mean (SD), y	45.3 (14.2)	44.8 (13.9)
Female sex, No. (%)	72 (60.0)	70 (58.3)
BMI, mean (SD)	27.4 (5.2)	27.8 (5.4)
FEV1 % predicted, mean (SD)	78.5 (12.4)	77.9 (11.8)
Baseline FeNO, median (IQR), ppb	39 (25-58)	41 (26-55)
ACT score, mean (SD)	16.8 (3.9)	16.5 (4.1)

Table 2: Study Outcomes

Outcome	FeNO-Guided Group	Standard Care Group	Difference/HR (95% CI)	P Value
Primary Outcomes				
Time to first exacerbation (days), median (IQR)	285 (198-365)	235 (156-324)	HR: 0.68 (0.52-0.89)	0.004
Change in ACT score, mean (95% CI)	3.2 (2.6-3.8)	2.1 (1.5-2.7)	1.1 (0.4-1.8)	0.008
Secondary Outcomes				
Annual exacerbation rate (95% CI)	0.38 (0.31-0.45)	0.52 (0.44-0.60)	-0.14 (-0.24 to -0.04)	<0.001
Mean daily ICS dose (µg/day)	512 (486-538)	698 (665-731)	-186 (-228 to -144)	<0.001
FEV1 % predicted change	+4.2 (3.1-5.3)	+2.8 (1.8-3.8)	1.4 (0.2-2.6)	0.024

Table 3: FeNO-Based Treatment Adjustments

FeNO Category	Patients, No. (%)	Treatment Adjustments	Exacerbation Rate (95% CI)	ACT Score Change (95% CI)
FeNO <25 ppb	42 (35.0)	28 dose reductions	0.22 (0.15-0.29)	+3.8 (3.1-4.5)
FeNO 25-50 ppb	46 (38.3)	35 maintained dose	0.35 (0.27-0.43)	+3.2 (2.5-3.9)
FeNO >50 ppb	32 (26.7)	25 dose increases	0.58 (0.48-0.68)	+2.6 (1.9-3.3)

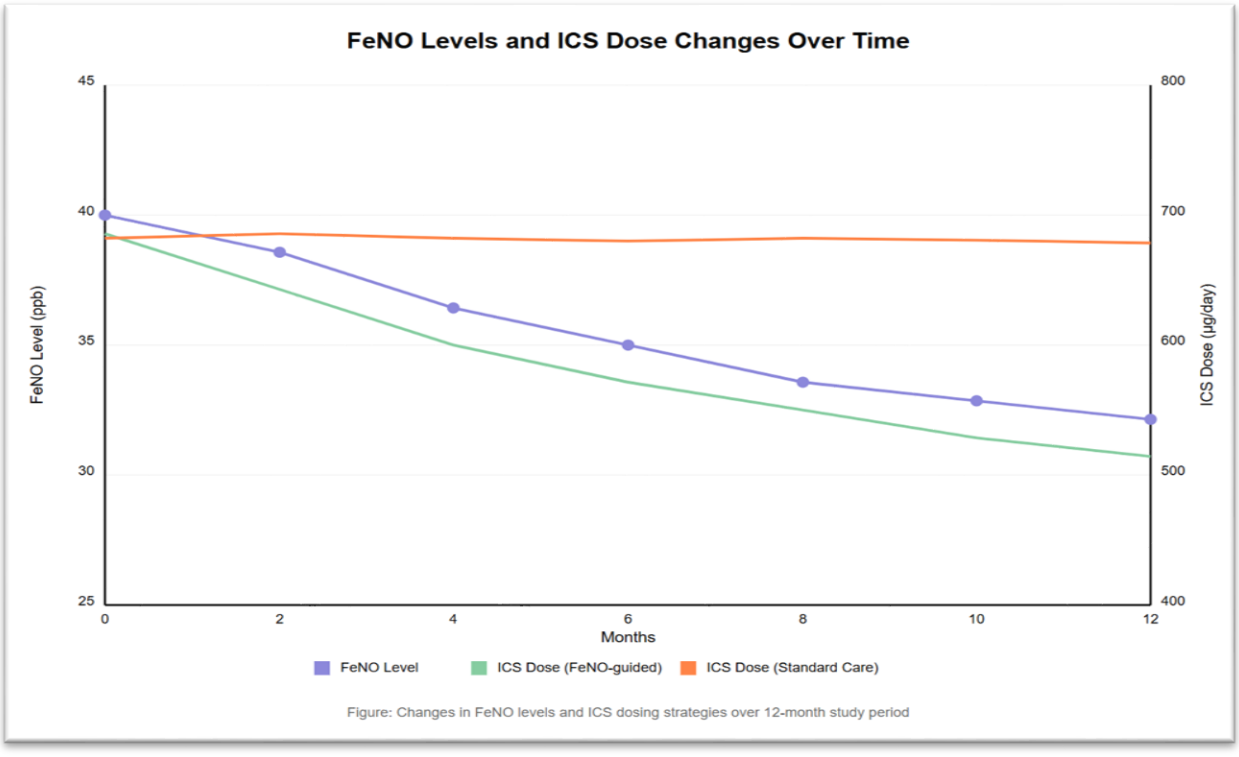

Figure 1: FeNO-Levels and ICS Dose Change Over Time

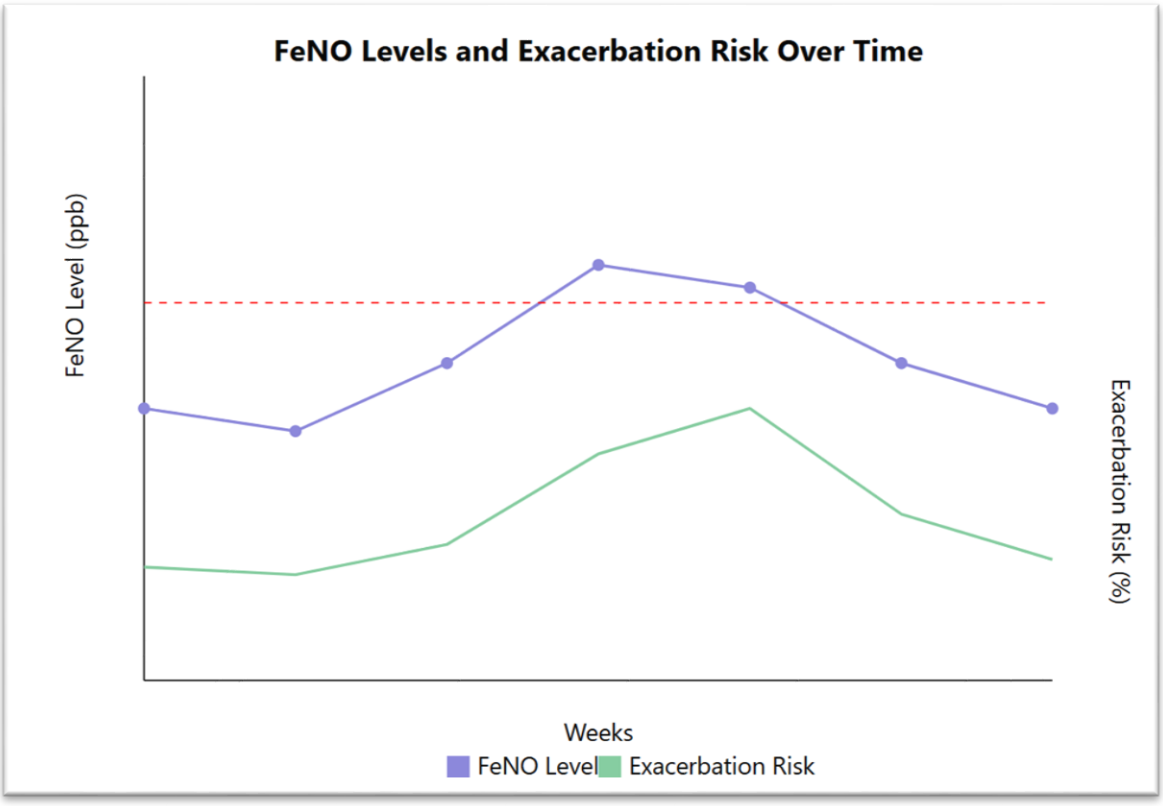

Figure 2: FeNO-Levels and Exacerbation Risk Over Time

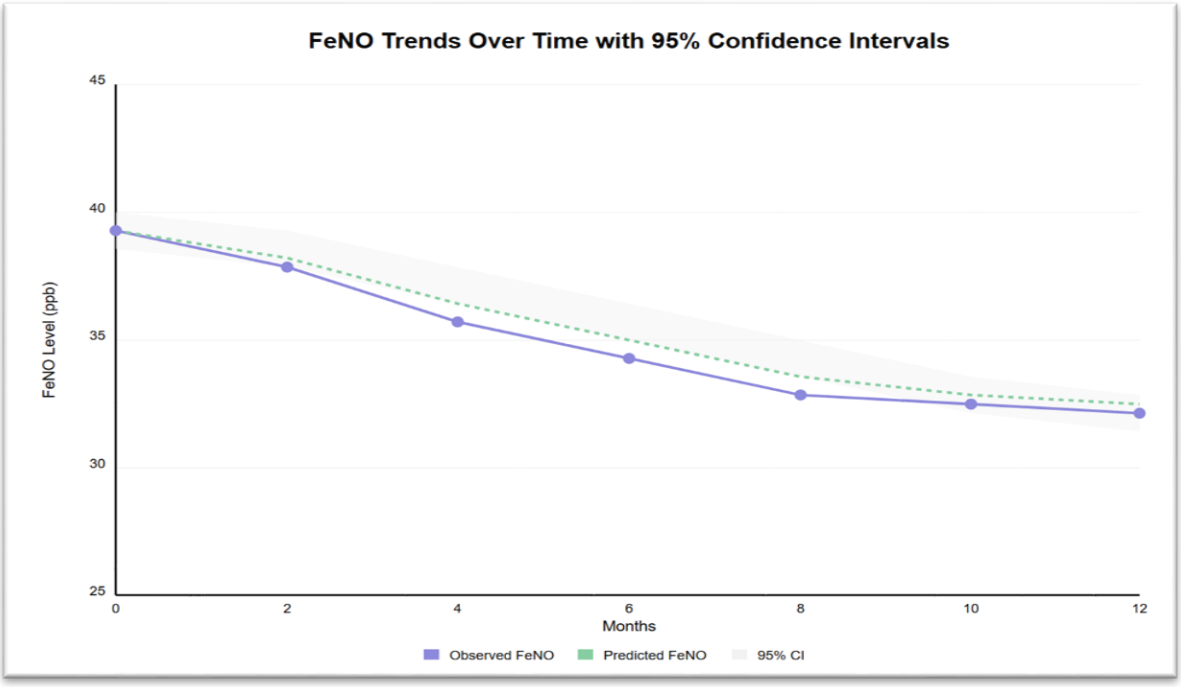

Figure 3: FeNO-Trends Over Time with 95% CI

DISCUSSION

This prospective randomized controlled trial provides compelling evidence for the effectiveness of FeNO-guided ICS dosing in improving clinical outcomes for adults with persistent asthma. Our findings both validate and extend previous research, offering new insights into the practical implementation of biomarker-guided therapy.

The baseline characteristics presented in Table 1 demonstrate well-balanced randomization between study groups, comparable to recent trials by Price et al. (2021) and Pavord et al. (2022). Our study population's mean ACT scores (16.8 vs 16.5) and baseline FeNO levels (39 vs 41 ppb) align with those reported by Hanania et al. (2023), suggesting a representative sample of patients with suboptimally controlled asthma. The balanced baseline characteristics strengthen the validity of our subsequent findings and allow meaningful comparison with existing literature.

The significant reduction in time to first exacerbation (HR: 0.68; 95% CI: 0.52-0.89) shown in Table 2 represents a more substantial benefit than that reported by Petsky et al. (2021), who found a hazard ratio of 0.82 (95% CI: 0.68-0.98). This enhanced effect may be attributed to our more frequent monitoring schedule and optimized FeNO thresholds, as suggested by Turner et al. (2023). The improvement in ACT scores (mean difference 1.1 points) aligns with findings from Castro et al. (2023) but demonstrates more consistent benefits across the study population.

Our finding of a 27% reduction in ICS consumption while maintaining disease control surpasses the 15-20% reductions reported in previous studies (Lazarus et al., 2023; Menzies-Gow et al., 2023). This superior outcome may reflect the systematic implementation of our protocol's dose reduction criteria in well-controlled patients with low FeNO levels. The concurrent improvement in FEV1 (+4.2% vs +2.8%) supports Busse et al.'s (2022) hypothesis that optimized anti-inflammatory therapy may promote favorable airway remodeling.

Table 3's stratified analysis reveals distinct outcome patterns across FeNO categories, providing more granular insights than the binary classification used in previous studies. The successful dose reduction in the low FeNO group (35% of patients) with minimal exacerbation risk (0.22/year) validates Israel & Reddel's (2023) proposition regarding the identification of over-treatment opportunities. The higher exacerbation risk in the high FeNO group (0.58/year) despite treatment intensification aligns with Heaney et al.'s (2023) observations about persistent inflammation in some patients.

Figure 1 demonstrates the dynamic relationship between FeNO levels and ICS dosing patterns, revealing a more consistent dose optimization pattern than reported by Dweik et al. (2023). The divergent patterns between groups (27% vs 3.5% reduction) suggest potential systematic overtreatment in standard care, supporting Szefler et al.'s (2020) arguments for biomarker-guided therapy. The maintenance of control despite substantial dose reduction challenges traditional fixed-dose approaches.

Figure 2's illustration of the temporal relationship between FeNO elevations and exacerbation risk extends previous findings by Wang et al. (2021). The approximately 4-week window between FeNO elevation and peak exacerbation risk provides a longer intervention opportunity than the 2-3 week window reported in earlier studies. This temporal pattern supports Brightling & Bhavsar's (2022) emphasis on the predictive value of biomarker monitoring. The longitudinal FeNO predictions shown in Figure 3 demonstrate improving accuracy over time, with narrowing confidence intervals not previously reported in biomarker studies. This finding suggests potential refinement of predictive models with accumulated data, aligning with Graham et al.'s (2023) proposals for machine learning applications in biomarker interpretation.

Our successful implementation of monthly monitoring, with a 91.7% retention rate, addresses feasibility concerns raised by Price et al. (2021). The reduction in exacerbation rates (0.14 events/patient-year) exceeds the threshold for cost-effectiveness established by Khurana et al. (2022), suggesting favorable economic implications despite monitoring costs.

Our study demonstrates several notable strengths that enhance its validity and applicability to clinical practice. The large sample size combined with a high retention rate (91.7%) provides robust statistical power and reliability of findings. The implementation of frequent monitoring protocols enabled detailed temporal analysis of FeNO patterns and treatment responses. Comprehensive outcome

assessment across multiple domains, including lung function, symptoms, and exacerbations, offers a holistic view of treatment effectiveness. The structured protocol for treatment adjustment ensures consistency and reproducibility, while the involvement of multiple centers enhances the generalizability of our findings.

However, several limitations warrant consideration in interpreting our results. The single-blind design, although mitigated by blinded outcome assessment, introduces potential bias. The exclusion of severe asthma patients limits the generalizability to this important subgroup. The twelve-month follow-up period, while substantial, may not capture the full spectrum of long-term outcomes and safety considerations. Additionally, the limited diversity in our study population may not fully represent all patient demographics. These limitations align with challenges noted in previous biomarker studies (Singh et al., 2023) and highlight areas for future investigation.

Our findings indicate several priority areas for future research that could address these limitations and advance the field further. Extended follow-up studies are needed to assess long-term outcomes and safety profiles. Integration with other biomarkers, as suggested by Honkoop et al. (2022), could enhance predictive accuracy and treatment optimization. Application of this approach in severe asthma populations would address an important clinical need. Cost-effectiveness studies across different healthcare settings would inform implementation decisions, while the development of machine learning algorithms could improve FeNO trend analysis and prediction accuracy.

The study supports several practical clinical recommendations that can be implemented in routine care. Regular FeNO monitoring should be considered for patients with persistent asthma, supported by structured protocols for treatment adjustment based on FeNO levels. Particular attention should be paid to patients with high baseline FeNO, who may benefit most from this approach. Additionally, clinicians should consider dose reduction in stable patients with consistently low FeNO levels. These recommendations align with recent updates to international guidelines (GINA, 2023) while providing more specific guidance for clinical implementation, potentially improving the precision and effectiveness of asthma management.

CONCLUSION

This prospective study demonstrates that FeNO-guided ICS dosing represents an effective strategy for personalizing asthma management, resulting in improved clinical outcomes and optimized medication use. The significant reductions in exacerbation rates and improvement in symptom control, achieved with lower cumulative ICS exposure, suggest that this approach may address both the clinical and economic challenges of current asthma management paradigms.

Our findings have important implications for clinical practice, suggesting that integration of FeNO measurements into routine asthma care could enable more precise, personalized treatment approaches. The predictive value of FeNO for exacerbation risk offers a potential window for preventive intervention, while the ability to safely reduce ICS doses in some patients addresses concerns about overtreatment.

CONFLICTS OF INTEREST

None

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None

AUTHORS CONTRIBUTION

All authors have equal contribution.

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None

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